Remarks

Claims 1-28, 29-54, 101, 110-117, 137-139, and 142-144 from co-pending application No. 09/967,603 are pending in the present application, as well as new claims 145-155. Applicants request reconsideration of the claim rejections raised in the July 10, 2003 action in view of the following remarks.

I. 35 U.S.C. § 102(b) Rejection of Claims 1-8, 11-16, 20, 23, 24, 26, 28, 30, 36-40, 42, 46-49, 53-54, 137, and 142

Claims 1-8, 11-16, 20, 23, 24, 26, 28, 30, 36-40, 42, 46-49, 53-54, 137, and 142 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,165,155 to Jacobsen et al. (Jacobsen). Applicants traverse this rejection and request that it be withdrawn.

Jacobsen is understood to disclose a drug delivery system that includes a module 20 designed to fit around an arm or leg of a user (FIG. 1). Module 20 has a series of drug delivery modules 62, 64, 66, 68 (FIG. 3). A sponge-like pad lies between the module 20 and the skin of the user, and provides double-sided adhesion to prevent movement of the module (col. 5, lines 54-57). One of the drug delivery modules of module 20 can be a transdermal diffusion drug delivery device 200 (FIG. 5). Device 200 is supported by an absorbent pad 370, which is positioned directly beneath an aperture 350 through which fluid is dispensed (FIG. 5 and col. 10, lines 40-43).

The claimed apparatus is an applicator for cutaneous delivery of a bioactive composition to a cutaneous target. The target can be a skin patch (e.g., a transdermal drug delivery patch) or skin if a patch is not provided (see paragraph 21 of the present application). The applicator includes a jet dispenser comprising an orifice, a container which holds the bioactive composition, and a spacer. The spacer is positioned between the dispenser orifice and the target during ejection of the bioactive composition.

One embodiment of the claimed apparatus is shown in FIGS. 1-3 of the present application. This embodiment comprises an applicator head 34 that includes spacer bars 36, 38 positioned to create a gap or spacing between ejection heads 40-46 from the upper exposed surface of a patch 25. The gap between the ejection heads and the patch permits a smooth, even application of fluid after the patch has swollen from soaking up the applied fluid. Additionally, this gap protects ejection heads 40-46 from unnecessarily coming into contact with the patch 25, which avoids forcing fibers or other debris from the surface of the patch into the nozzles of the applicator. Adequate spacing between the ejection heads and the patch also avoids capillary wicking of the fluid from the nozzles, which can result in inadvertent or unwanted administration of fluid to the patch. See paragraph 41 of the present application.

In contrast to the claimed apparatus, Jacobsen neither teaches nor suggests an applicator having a dispenser orifice and a spacer positioned between the dispenser orifice and a target during ejection of a bioactive composition to the target, as recited in claim 1.

In the rejection of claim 1, the Examiner contends that the Jacobsen device includes a spacer comprising a sponge that is supported by the dispenser (see action, page 5). Applicants respectfully disagree with this contention. In the transdermal delivery device 200 of Jacobsen (FIG. 5), the sponge is understood to comprise pad 370 positioned to absorb fluid flowing from aperture 350. Thus, in the Jacobsen device, pad 370 serves as the target for the applied fluid. Unlike the claimed apparatus, the Jacobsen device does not include a spacer positioned between the orifice and the target (i.e., pad 370). Thus, Jacobsen does not show each and every feature of the claimed apparatus..

Further, as shown in FIG. 5 of Jacobsen, pad 370 is positioned to directly contact the lower wall 360 that defines aperture 350. In this configuration, there is no gap or spacing below the aperture 350 that protects against capillary wicking of fluid from the aperture and against fibers or other debris from the pad from being forced into the aperture. Jacobsen fails to provide any disclosure on how to maintain a gap or spacing between aperture 350 and pad 370 and why such a gap would be desirable.

For at least the foregoing reasons, claim 1 is not anticipated or rendered obvious by Jacobsen and is allowable.

Claims 2-8, 11-16, 20, 23, 24, 26, 28, 30, 36-40, 42, 46-49, 53-54, 137, and 142 depend from claim 1 and are allowable for the reasons set forth above in support of claim 1 and because each dependent claim recites an independently patentable combination of features.

For example, Jacobsen neither teaches nor suggests an applicator having a jet dispenser and multiple container modules that are removable from the jet dispenser, as recited in claim 14. In contrast to the claimed apparatus, the Jacobsen device is understood to include multiple drug delivery dispensers (e.g., dispensers 200, 400, or 450 shown in FIGS. 5-7, respectively) that are individually removable from module 20 (col. 3, lines 37-42). Each drug delivery dispenser is an integral unit formed with a chamber (e.g., chamber 300 of FIG. 5) (which serves as a container for a drug) and a dispensing aperture (e.g., aperture 350 of FIG. 5). As Jacobsen is presently understood, each drug deliverly dispenser (e.g., dispenser 200, 400, or 450) can be removed from module 20 (FIG. 1), but the individual chambers are integral with and therefore cannot be removed from their respective dispensers.

Jacobsen also does not teach or suggest a spacer comprises a sealing member that selectively substantially seals the dispenser against the target to form a substantially closed chamber, as recited in amended claim 26. The Office action states that the seal in the Jacobsen device is the adhesive on the absorbent sponge (e.g., sponge 370 in FIG. 5) positioned underneath the dispenser (see action, page 5). However, as shown in FIG. 5 of Jacobsen, when dispenser 200 is positioned on a leg or arm of a user, pad 370 is sandwiched between lower wall 360 and the skin of the user. Pad 370 and/or the adhesive on the pad clearly do not form a chamber when the dispenser is placed against the target.

Jacobsen also does not teach or suggest an indicator which indicates a degree of depletion of the bioactive composition in the dispenser, as recited in claim 28. The Office action states at page 6 that Jacobsen's display screen 50 is considered to be an indicator (see action, page 6). Jacobsen's display screen allegedly displays various information stored in memory 52 (col. 7, lines 10-11). However, at not point does Jacobsen teach or suggest indicating a degree of depletion of a bioactive composition from a dispenser, as recited in claim 28.

Additionally, Jacobsen does not teach or suggest a reservoir containing the bioactive composition and a fluid conduit to convey the bioactive composition from the reservoir to the jet dispenser, as recited in claim 142. In the rejection of claim 142, the Examiner contends that Jacobsen discloses "a reservoir ([70], 72, 74, or 76) fluidically connected to the jet dispensers (62, 64, 66, or 68) (fig. 3)." Applicants agree that FIG. 3 schematically depicts fluid reservoirs as being fluidically connected to respective dispensers. However, there is no disclosure in Jacobsen for a reservoir that is fluidically connected to a dispenser via a fluid conduit. As shown in FIG. 5 of Jacobsen, the fluid chamber 300 is formed with a dispensing aperture 350 formed in the chamber lower wall 360. Thus, in this configuration, there is no fluid conduit conveying fluid between chamber 300 and orifice 350.

III. 35 U.S.C. § 103(a) Rejection of Claim 9

Claim 9 stands rejected under 35 U.S.C. § 103(a) as allegedly being obvious from Jacobsen in view of U.S. Patent No. 6,436,078 to Svedman. Applicants traverse this rejection and requests that it be withdrawn.

Claim 9 depends from claim 1 and is allowable for the reasons set forth above in support of claim 1 and because claim 9 recites an independently patentable combination of features.

IV. 35 U.S.C. § 103(a) Rejection of Claim 10

Claim 10 stands rejected under 35 U.S.C. § 103(a) as allegedly being obvious from Jacobsen in view of U.S. Patent No. 5,894,841 to Voges. Applicants traverse this rejection and requests that it be withdrawn.

Claim 10 depends from claim 1 and is allowable for the reasons set forth above in support of claim 1 and because claim 10 recites an independently patentable combination of features.

V. Conclusion

The present application is in condition for allowance and such action is respectfully requested. If any further issues remain concerning this application, the Examiner is requested to call the undersigned to discuss such matters.

Respectfully submitted,

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